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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,754	10/20/2000	Neil Berinstein	13115	7885

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EXAMINER
BECKERLEG, ANNE M

ART UNIT	PAPER NUMBER
1632	7

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/693,754	Applicant(s) BERINSTEIN ET AL.	
	Examiner Anne M Beckerleg	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply* .

DETAILED ACTION

Nucleotide and/or amino acid sequences

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures which is attached to this communication. Applicant is requested to return a copy of the attached Notice To Comply with the response.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hurpin et al. (1998) Vaccine, Vol. 16 (2/3) 208-215. The applicant claims methods for inducing

an immune response in an animal to a tumor antigen comprising administering a nucleic acid to a lymphatic site in an animal. The applicant further claims said methods wherein the tumor antigen is selected from a group which includes p53 and wherein the nucleic acid is selected from a group which includes the canarypox nucleic acid, ALVAC.

Hurpin et al. teaches the generation of anti-53 CTL responses in mice following intrasplenic injection of ALVAC encoding p53 (Hurpin et al., page 211, Figure 1). Thus, by teaching all the elements of the claims, Hurpin et al. anticipates the instant invention.

Claims 1-17 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/02183, 1/21/99, hereafter referred to as Kundig et al.. The applicant claims methods for inducing an immune response in an animal to a tumor antigen comprising administering a tumor antigen to a lymphatic site. The applicant further claims said methods wherein the tumor antigen is a peptide or protein, wherein the tumor antigen is expressed by a viral nucleic acid or DNA, wherein the tumor antigen is gp100, or wherein the lymphatic site is a lymph node. Please note that the claims also read in the alternative such that the instant method can be practiced with *either* a tumor antigen peptide or a nucleic acid encoding the peptide. Claims 5-8, and 11-14 have been included in this rejection based on the alternative of administering a tumor antigen peptide.

Kundig et al. teaches methods of inducing an immunological CTL response in a mammal comprising delivering an antigen directly to a lymph node (Kundig et al., page 66, claim 3). Kundig et al. further teaches said methods wherein the antigen is a tumor antigen such as gp100 or CEA (Kundig et al., page 67, claim 19). In addition, Kundig et al. teaches that the antigen can

be delivered in the form of a viral vector or DNA (Kundig et al., page 53, lines 11-17). Thus, by teaching all the elements of the claims, Kundig et al. anticipates the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/02183, 1/21/99, hereafter referred to as Kundig et al, in view of Zaremba et al. (1997) Canc. Res., Vol. 57, 4570-4577 and Salgaller et al. (1996) Canc. Res., Vol. 56, 4749-4757. The applicant claims methods for inducing an immune response in an animal to a tumor antigen

comprising administering a nucleic acid to a lymphatic site in an animal. The applicant further claims said methods wherein the tumor antigen comprises the sequence YLSGADLNL or YLEPGPVTV. Kundig et al. teaches methods of inducing an immunological CTL response in a mammal comprising delivering an antigen directly to a lymph node (Kundig et al., page 66, claim 3). Kundig et al. further teaches said methods wherein the antigen is a tumor antigen such as gp100 or CEA (Kundig et al., page 67, claim 19). While Kundig et al. lists numerous peptide epitopes for use in the disclosed methods, including the gp100 epitope YLEPGPVTA, they do not specifically disclose the use of the modified peptides YLSGADLNL or YLEPGPVTV derived from the CEA or gp100 antigens respectively.

Zaremba et al. supplements Kundig et al. by teaching that the YLSGADLNL epitope is a CTL enhancer agonist peptide for inducing potent anti-CEA CTL (Zaremba et al., page 4570, abstract). Zaremba et al. further provides motivation for using the modified CEA peptide to induce anti-CEA CTL by teaching that the YLSGADLNL peptide is more potent that the unmodified YLSGANLNL peptide in inducing anti-CEA CTL (Zaremba et al., page 4574). Sangeller et al. further supplements Kundig et al. by teaching a modified gp100 peptide YLEPGPVTV, which also demonstrates an enhanced ability to generate anti-gp100 CTL than the unmodified YLEPGPVTA peptide (Sangeller et al., page 4749, abstract and column 2). Thus, based on the motivation provided by Zaremba et al. and Sangeller et al. that the modified peptides YLSGADLNL and YLEPGPVTV are more potent than the unmodified parent peptides at generating anti-CEA or anti-gp100 CTL respectively, it would have been *prima facie* obvious to the skilled artisan at the time of filing to substitute the modified YLSGADLNL or YLEPGPVTV

peptides for the unmodified CEA and gp100 peptides taught by Kundig et al., and further to use those peptides for immunizing a mammal by intranodal injection as taught by Kundig et al. with a reasonable expectation of success.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Beckerleg, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Karen Hauda, can be reached at (703) 305-6608. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The official fax number is (703) 308-4242.

Dr. A.M.S. Beckerleg

A.M.S. BECKERLEG.
PATENT EXAMINER

Application No.: 09/693,754

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE